

CLAIMS

- 1. Film-shaped preparation disintegratable in aqueous media, for administration of substances to the human or animal body, containing at least one water-soluble polymer, characterized in that said preparation contains one or more components which produce a gas upon action of moisture or in the presence of an aqueous medium or in the case of a change in temperature.
- 2. Film-shaped preparation according to one or more of the preceding claims, characterized in that the gas-forming component(s) are selected from the group comprising carbonates, especially sodium carbonate, ammonium carbonate, magnesium carbonate, potassium carbonate, and hydrogen carbonate, especially sodium hydrogen carbonate, and acids, especially citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid, tartaric acid, as well as acid regulators, especially salts of acetic acid, sodium dihydrogen phosphate or disodium hydrogen phosphate, sodium tartrate, sodium ascorbate.
- 3. Film-shaped preparation according to claim 2, characterized in that it contains a combination of at least one gas-forming component (a) and at least one gas-forming component (b), said component(s)
- (a) being selected from the group of the carboxylic acids, preferably from the group comprising citric acid, malic acid, acetic acid, lactic acid, fumaric acid, gluconic acid and tartaric acid, and the component(s)



- (b) being selected from the group comprising sodium hydrogen carbonate, sodium carbonate, potassium carbonate and potassium hydrogen carbonate.
- 4. Film-shaped preparation according to one or more of the preceding claims, characterized in that it is capable of producing CO_2 or N_2 , preferably under action of water or an aqueous medium or moisture.
- 5. Film-shaped preparation according to one or more of the preceding claims, characterized in that it produces an acid environment in the presence of water.
- 6. Film-shaped preparation according to one or more of the preceding claims, characterized in that it disintegrates in the presence of water or an aqueous medium within 1 s to 5 min, preferably within 1 s to 1 min, especially preferably within 1 s to 30 s.
- 7. Film-shaped preparation according to one or more of the preceding claims, characterized in that it is swellable in aqueous media.
- 8. Film-shaped preparation according to one or more of the preceding claims, characterized in that it contains a pharmaceutical active substance or a combination of two or more pharmaceutical active substances.
- 9. Film-shaped preparation according to one or more of the preceding claims, characterized in that it contains at least one flavouring agent, preferably menthol.



- 10. Film-shaped preparation according to one or more of the preceding claims, characterized in that it comprises at least two layers.
- 11. Film-shaped preparation according to one or more of the preceding claims, characterized in that it has a thickness between 5 μm and 3 mm, preferably between 10 μm and 1 mm, especially preferably between 20 μm and 500 μm .
- 12. Use of a preparation according to one or more of the preceding claims for oral, rectal or vaginal administration of pharmaceutical active substances.
- 13. Process for the production of a preparation according to one or more of claims 1 to 11 by coating a coating compound on a support, comprising the steps of:
- preparing a coating compound which contains the components of the preparation including the gasforming component(s) by dissolving or suspending the components in a solvent or suspending agent that is substantially free from water;
- spreading this coating compound on a support and drying.
- 14. Process for the production of a preparation according to one or more of claims 1 to 11 by coating a coating compound on a support, comprising the steps of:
- preparing a coating compound which contains the components of the preparation including the gasforming component(s) by melting said components;

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- extruding the molten coating compound onto the support through slot dies.
- 15. Process for the production of a preparation according to one or more of claims 1 to 11 for coating a coating compound on a support, comprising the steps of:
- preparing a first coating compound which contains a first gas-forming component as well as further components of the film-forming preparation by dissolving or suspending said components in an aqueous solvent or suspending agent;
- preparing a second coating compound which contains a second gas-forming component as well as further components of the film-shaped preparation by dissolving or suspending said components in an aqueous solvent or suspending agent, said first and said second component being reaction partners of a gas-forming reaction;
- spreading the first coating compound on a support and drying, thus forming a first film;
- spreading the second coating compound on a support and drying, thus forming a second film;
- laminating the two films onto each other.
- 16. Process for the production of a preparation according to one or more of claims 1 to 11 by coating a coating compound on a support, comprising the steps of:
- preparing a coating compound which contains the components of the preparation including the gasforming components by dissolving or suspending the said components in a solvent or a suspending agent,

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with at least one of the gas-forming components being present in microencapsulated form; spreading this coating compound on a support and drying.